UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to: *Broward County, Florida v. Purdue Pharma L.P.*, No. 18-op-45332

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

DECLARATION OF MARK S. CHEFFO IN SUPPORT OF THE MANUFACTURER DEFENDANTS' JOINT MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED $\underline{\text{COMPLAINT}}$

I, Mark S. Cheffo, declare as follows:

1. I am a partner at the law firm of Dechert LLP and counsel of record for Defendants

Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company in the above-

captioned matter. I am a member in good standing of the State Bar of New York. I submit this

declaration in support of the Manufacturer Defendants' Joint Motion to Dismiss Plaintiff's Second

Amended Complaint. I have personal knowledge of the following facts and, if called and sworn as

a witness, could and would testify competently thereto.

2. Attached hereto as **Exhibit 1** is a true and correct copy of a complaint filed by the

State of Florida, Office of The Attorney General, Department of Legal Affairs on May 15, 2018

in the Circuit Court of the Sixth Judicial Circuit, Florida.

3. I declare under penalty of perjury that the foregoing is true and correct. This

Declaration was executed in New York, New York, on June 8, 2018.

Dated: June 8, 2018 By: /s/ Mark S. Cheffo

Mark S. Cheffo

DECHERT LLP

Three Bryant Park 1095 Avenue of the Americas New York, NY 10036 Tel: (212) 698-3500 Mark.Cheffo@dechert.com

Attorney for Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company

CERTIFICATE OF SERVICE

I hereby certify that on the 8th of June, 2018, I electronically filled the forgoing with the Clerk of the Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF systems.

Dated: June 8, 2018 By: /s/ Mark S. Cheffo

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EXHIBIT 1

IN THE CIRCUIT COURT OF THE SIXTH JUDICIAL CIRCUIT IN AND FOR PASCO COUNTY, WEST PASCO DIVISION NEW PORT RICHEY, FLORIDA

Case No. _____

STATE OF FLORIDA, OFFICE OF THE ATTORNEY GENERAL, DEPARTMENT OF LEGAL AFFAIRS,

L AFFAIRS,

Plaintiff,

JURY TRIAL DEMANDED

v.

PURDUE PHARMA L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., ALLERGAN PLC, ALLERGAN FINANCE, LLC, ACTAVIS PLC, ACTAVIS PHARMA, INC., ACTAVIS LLC, AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., MCKESSON CORPORATION, MALLINCKRODT PLC, and MALLINCKRODT LLC,

Defendants.	

COMPLAINT

Plaintiff, the State of Florida, Office of the Attorney General, Department of Legal Affairs ("State of Florida"), sues Defendants, Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Cephalon, Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., Allergan plc, Allergan Finance, LLC, Actavis PLC,

Actavis Pharma, Inc., Actavis LLC, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, Mallinckrodt plc, and Mallinckrodt LLC, and alleges as follows:

I. Introduction

- 1. The State of Florida is suffering from a devastating opioid crisis created by the Defendants. Opioids caused 5,725 deaths in Florida in 2016, an average of more than 15 Floridian deaths every day from opioids.¹ Opioids could kill as many as 500,000 people in the United States over the next ten years.² Governor Rick Scott declared a state of emergency in Florida on May 3, 2017, as a result of the opioid epidemic.³
- 2. Opioids are powerful narcotic painkillers that include non-synthetic, partially synthetic, and fully-synthetic derivatives of the opium poppy. Use of prescription opioids can cause addiction, overdose, and deaths. Defendants manufacture or distribute opioids under a variety of brand names.
- 3. Opioid addiction has destroyed the lives of tens of thousands of Floridians and caused immense pain and suffering for families throughout Florida. Pasco County has consistently ranked amongst the hardest hit areas of the State throughout the entirety of the opioid crisis. From 2004 through 2012, as the pill mill epidemic ravaged the State, Pasco County experienced Florida's highest drug overdose mortality rate.
- 4. According to the Florida Department of Law Enforcement, in 2016, District 6, which is Pasco and Pinellas Counties, experienced the highest number of oxycodone deaths in Florida.

See Drugs Identified in Deceased Persons, Florida Department of Law Enforcement, November 2017.

² See https://www.statnews.com/2017/06/27/opioid-deaths-forecast.

State of Florida, Office of the Governor, Executive Order Number 17-146.

- 5. In 2016, the Pasco County Sheriff's Office administered opioid addiction treatment to nearly 2,000 inmates.
- 6. In 2017, someone overdosed in Pasco County an average of once every three days.
- 7. The disproportionately high overdose rates were the direct, readily foreseeable result of the shockingly high amounts of opioids which have been funneled into Pasco County throughout the crisis. For example, a single pharmacy in Hudson, Florida—a Pasco County town of 34,000 people—purchased 2.2 million opioid pills in just one year (2011). That same year, another pharmacy dispensed more than 1.4 million opioids in Port Richey, Florida.
- 8. Broward County recorded 582 opioid overdose deaths in 2017 alone, up from 545 deaths in 2016. In a single day last year, ten people died of overdoses in Palm Beach County. In Manatee County, the opioid crisis is so severe that the medical examiner reported in 2017 that the morgue ran out of space for the bodies of opioid overdose victims.
- 9. The Manufacturer Defendants caused the opioid epidemic by engaging in a strategic campaign of misrepresentations about the risks and benefits of opioid use to physicians, other prescribers, consumers, pharmacies, and state governmental agencies. The Manufacturer Defendants knew that opioids were dangerous and addictive; nevertheless, they collectively used front organizations that they funded to disseminate misinformation about the use of opioids for chronic pain treatment. The Manufacturer Defendants also employed medical professionals known as key opinion leaders ("KOLs") to endorse and promote the use of opioids. The KOLs wrote articles and gave speeches touting the benefits of opioid use as if they were independent medical experts, but they actually served as the Manufacturer Defendants' mouthpieces.

- 10. The Distributor Defendants caused the opioid crisis by violating their duties under Florida law to monitor, report, and stop suspicious orders of opioids from their customers in Florida. The Distributor Defendants also assisted the Manufacturer Defendants with their opioid marketing.
- 11. Because they are so dangerous and addictive, Florida imposes obligations on both manufacturers and distributors of opioids aimed at preventing the misuse of these drugs and their diversion into the marketplace for uses other than legitimate medical uses. Because of the actions of the Defendants in violating these duties, the closed chain of supply broke down in Florida, leading to a massive public health crisis that continues to ravage the State.
- 12. The State of Florida has sustained and continues to suffer massive losses as a result of this opioid epidemic through loss of lives, babies born addicted to opioids, adults unable to work, treatment costs, emergency personnel costs, law enforcement expenses, naloxone costs, medical examiner expenses, foster care expenses, self-funded state insurance costs, and lost tax revenues, among many other costs.
- 13. The State of Florida brings this civil action to hold the Defendants accountable for unconscionably creating the State of Florida's opioid public health and financial crisis. The Defendants reaped billions of dollars in revenues while causing immense harm to the State of Florida and its citizens, and now they must pay for their role in the crisis and act to remediate the crisis.

II. Nature of the Action

14. The State of Florida brings this action against all Defendants under the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), the Florida Racketeer Influenced and

Naloxone is used to block the effects of opioids in overdose cases.

Corrupt Organization Act ("Florida RICO"), Fla. Stat. § 895.01 et seq., and for public nuisance.

15. The State of Florida also brings an action against the Distributor Defendants for both negligence and negligence *per se*.

III. Jurisdiction and Venue

- 16. This Court has jurisdiction pursuant to FDUTPA, Florida RICO, and common law causes of action.
- 17. The statutory violations alleged herein occurred in or affected more than one judicial circuit in the State of Florida.
- 18. Venue is proper in the Sixth Judicial Circuit for West Pasco County, Florida because the causes of action arose at least in part in New Port Richey, Port Richey, and Hudson, Florida, Defendants transacted business in New Port Richey, Port Richey, and Hudson, Florida, and some of the conduct alleged herein occurred in New Port Richey, Port Richey, and Hudson, Florida. Moreover, the West Pasco courthouse is the nearest Pasco County courthouse to the Florida Attorney General's headquarters in Tallahassee, Florida and its principal regional office in Tampa, Florida.
- 19. The Office of the Attorney General is the enforcing authority or the proper party to assert all causes of action alleged herein.
- 20. The Office of the Attorney General has conducted an investigation and the head of the enforcing authority, Attorney General Pam Bondi, has determined that an enforcement action serves the public interest pursuant to Chapter 501, Part II, Florida Statutes.

IV. Parties

A. Plaintiff

21. The Department of Legal Affairs of Florida is the enforcing authority for

violations of FDUTPA and has the authority to file Count I seeking the full range of relief afforded by Chapter 501, Florida Statutes.

- 22. The Attorney General of Florida is the chief legal officer of Florida and the enforcement authority of Florida RICO and is authorized to file Count II seeking the full range of relief afforded by Chapter 895, Florida Statutes.
- 23. The State of Florida is authorized to file Count III for common law public nuisance and pursuant to Chapter 823 and Chapter 60, Florida Statutes.
- 24. The State of Florida is authorized to file Count IV for negligence and Count V for negligence *per se*.
- 25. In this lawsuit, the State of Florida does not seek to enforce or make a claim against any Defendant under any federal statute or regulation.

B. Defendants

1. Manufacturer Defendants

- 26. Defendant Purdue Pharma L.P is a limited partnership organized under the laws of the State of Delaware. Defendant, Purdue Pharma, Inc., is a New York corporation with its principal place of business in Connecticut. Defendant, The Purdue Frederick Company, Inc., is a New York corporation with its principal place of business in Connecticut. These Defendants are collectively referred to herein as "Purdue."
- 27. Purdue manufactures the opioids OxyContin, MS Contin, Butrans, Hysingla ER, Dilaudid, and Dilaudid-HP. Purdue promotes, markets, advertises, and sells a number of opioids in Florida, including OxyContin, MS Contin, Butrans, Hysingla ER, Dilaudid, and Dilaudid-HP.
 - 28. Defendants Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are

both Delaware corporations with their principal places of business in Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions, Inc. These Defendants are collectively referred to herein as "Endo."

- 29. Endo manufactures the opioids Percocet, Opana, and Percodan. Endo promotes, markets, advertises, and sells opioids in Florida, including Percocet and Opana, and previously Opana ER.
- 30. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in New Jersey. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson, which controls the sale and development of Janssen Pharmaceuticals, Inc.'s drugs. Janssen Pharmaceuticals, Inc.'s profits inure to Johnson & Johnson's benefit. Janssen Pharmaceuticals, Inc. and Johnson & Johnson are collectively referred to herein as "Janssen."
- 31. Janssen manufactures the opioids Duragesic and Tapentadol IR and previously manufactured the opioids Nucynta and Nucynta ER. Janssen promotes, markets, advertises, and sells opioids in Florida, including Duragesic and Tapentadol IR. Until 2015, Janssen promoted, marketed, advertised, and sold the opioids Nucynta and Nucynta ER in Florida.
- 32. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Defendant Actavis PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in June 2015.
- 33. Defendant Allergan Finance, LLC is a Nevada limited liability company located in New Jersey and is a wholly owned subsidiary of Allergan plc.
 - 34. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal

place of business in New Jersey. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in New Jersey.

- 35. Defendant Allergan Finance, LLC is owned by Allergan plc. Until August 2016 when they were sold to Teva, Actavis Pharma, Inc. and Actavis LLC were owned by Allergan plc. Allergan plc uses Allergan Finance, LLC to market and sell its drugs in the United States. Until August 2016, Allergan plc used Actavis Pharma, Inc. and Actavis LLC to market and sell its drugs in the United States. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts, and profits from the sales of Allergan/Actavis products. Allergan plc, Allergan Finance LLC, Actavis PLC, Actavis, Inc., Actavis LLC, and Actavis Pharma, Inc. are collectively referred to herein as "Allergan."
- 36. Allergan manufactures the opioids Kadian and Norco. Allergan promotes, markets, advertises, and sells opioids in Florida, including Kadian and Norco. Allergan also has sold generic versions of Kadian, Duragesic, and Opana.
- 37. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.
- 38. Defendant Teva USA ("Teva USA") is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA promoted, marketed, advertised, and sold opioids in Florida and nationwide, including generic Oxycontin.
- 39. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikvah, Israel. Defendant Teva USA is a wholly-owned subsidiary of Teva Ltd. In 2011, Teva Ltd. acquired Cephalon, Inc. Since Teva Ltd. acquired Cephalon, Inc., its United States sales and marketing activities have been conducted by Teva USA. Teva USA, Teva Ltd., and Cephalon, Inc. are collectively referred to

herein as "Cephalon."

- 40. Defendants Purdue Pharma L.P., Purdue Pharma, Inc., The Purdue Frederick
 Company, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen
 Pharmaceuticals, Inc., Johnson & Johnson, Cephalon, Inc., Teva Pharmaceuticals USA, Inc.,
 Teva Pharmaceutical Industries Ltd., Allergan plc, Allergan Finance, LLC, Actavis PLC,
 Actavis Pharma, Inc., and Actavis LLC are collectively referred to herein as the "Manufacturer Defendants."
- 41. At all relevant times, the Manufacturer Defendants promoted, marketed, advertised, and sold opioids in the State of Florida to consumers, physicians, other prescribers, and state governmental agencies.

2. Distributor Defendants

- 42. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business in Chesterbrook, Pennsylvania.

 AmerisourceBergen operates distribution and/or warehouse centers in Florida, including Orlando.
- 43. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal place of business in Dublin, Ohio. Cardinal operates distribution and/or warehouse centers in Florida, including Lakeland, Jupiter, Pompano Beach, Weston, Tampa, and Jacksonville.
- 44. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson operates distribution and/or warehouse centers in Florida, including Orlando, Lakeland, and Jacksonville.
 - 45. Defendant Mallinckrodt plc is an Irish public limited company with its

headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc also operates under the registered name of Mallinckrodt Pharmaceuticals with its U.S. headquarters in Hazelwood, Missouri. Defendant Mallinckrodt LLC is a Delaware limited liability company headquartered in Missouri. Defendants Mallinckrodt plc and Mallinckrodt LLC are collectively referred to herein as "Mallinckrodt." Mallinckrodt maintains an office in Florida.

- 46. Defendants AmerisourceBergen, Cardinal, McKesson, and Mallinckrodt are collectively referred to herein as the "Distributor Defendants."
- 47. The Distributor Defendants collectively make up approximately 85% of the opioid distribution market nationwide.
- 48. At all relevant times, the Distributor Defendants distributed opioids in the State of Florida to Florida pharmacies, which were then purchased by Florida consumers and Florida governmental agencies.

V. Factual Allegations

A. Opioids are Dangerous and Highly Addictive Narcotics.

- 49. Opioids are highly addictive narcotics. The risk of becoming addicted for people taking prescription opioids for pain is very high. Elderly people who take opioids are not at lower risk of addiction. Engaging in demanding or manipulative behavior to obtain opioids is a sign of addiction. Defendants were aware that opioids are highly addictive.
- 50. High-dose and long-term prescription of opioids for chronic pain present particular dangers. Risks of opioid usage include overdose, respiratory depression, hyperalgesia, hormonal dysfunction, neonatal abstinence syndrome, decline in immune function, confusion, dizziness (and increased falls and fractures in the elderly), and potentially fatal interactions with alcohol or benzodiazepines. People who become addicted to prescription

opioids are at higher risk of becoming addicted to drugs that have no lawful uses, including heroin.

- 51. Opioids can interact very dangerously with benzodiazepines, a common treatment for veterans with PTSD.
- 52. Because many people become addicted to opioids, they are at risk of being diverted from lawful, controlled medical uses into the illegal drug market.
 - B. The Manufacturer Defendants Used a Campaign of Misrepresentations to Increase Opioid Prescriptions and Opioid Use among the General Public.
- 53. The Manufacturer Defendants promoted misrepresentations about the use of opioids to physicians, other prescribers, and consumers that were designed to increase opioid prescriptions and opioid use.
- 54. The Manufacturer Defendants funded front organizations that appeared to be neutral, third-party patient advocacy groups and professional associations that promoted the use of opioids as safe and effective for chronic pain treatment without disclosing known risks of opioid treatment. The front organizations published literature for patient education on pain management and pain treatment. These publications were used by the Manufacturer Defendants to influence the decisions of prescribers and patients.
- 55. The Manufacturer Defendants also funded key opinion leaders ("KOLs"), medical experts who were able to influence their peers because of their reputations. The KOLs appeared to be independent actors to lend legitimacy to their opinions, leading to doctors and their patients more readily accepting their claims. However, the Manufacturer Defendants supported the KOLs by paying them to speak at conferences, paying them consulting fees, travel and lodging expenses, and food and beverage expenses if they continued to tout the use of opioids for chronic pain relief.

- 56. The Manufacturer Defendants used continuing medical education programs ("CMEs") to spread misinformation. These CMEs spread the Manufacturer Defendants' false messages to doctors under the guise of legitimate educational programs.
- 57. The Manufacturer Defendants encouraged their sales forces to misrepresent the addictive qualities of opioids through training programs. For example, the *American Journal of Public Health* noted, "Purdue trained its sales representatives to carry the message that the risk of addiction was 'less than one percent." A Janssen training module instructed that physicians were generally unwilling to prescribe Nucynta and other opioids, but their reluctance was unfounded because the risks were "much smaller than commonly believed."
- 58. The Manufacturer Defendants sponsored publications that spread the campaign of misinformation about opioids including: *Understanding Your Pain: Taking Oral Opioid*Analgesics; Getting the Help You Need; A Policymaker's Guide to Understanding Pain & Its

 Management; Treatment Options: A Guide for People Living with Pain (2007); Finding Relief:

 Pain Management for Older Adults (2009); Exit Wounds; and Responsible Opioid Prescribing.
- 59. The Manufacturer Defendants promoted their opioid products through misrepresentations on websites including: www.opana.com; www.PainAction.com; painknowledge.com; www.opana.com; <a href="www.opana.com"
 - C. The Manufacturer Defendants Made Numerous Misrepresentations and Omitted Material Facts about the Use of Opioids.
- 60. The Manufacturer Defendants misrepresented and omitted material facts about the use of opioids to physicians, other prescribers, and consumers in Florida.
 - 61. The Manufacturer Defendants misrepresented:
 - a. the risks of developing opioid addiction;
 - b. the signs of opioid addiction;

- c. the difficulties of preventing opioid addiction;
- d. the signs of opioid addiction were merely symptoms of "pseudoaddiction" that needed to be treated by increased dosages of opioids;
- e. the dangers of high-dose opioid treatment;
- f. that taking opioids long-term for chronic pain would lead to increased lifestyle benefits while omitting the risks of such treatment;
- g. the risk of addiction for the elderly was lower than the general population;
- h. the risk of addiction for veterans and omitting the severe risks of taking opioids with benzodiazepines, a common treatment for PTSD;
- i. the risks and benefits of non-opioid pain relief treatments while omitting material risks of taking opioids;
- j. that certain opioid products were less likely to be misused; and
- k. that certain opioids were to be used to treat "breakthrough pain" while omitting severe side effects.

D. Misrepresentations and Omissions by Each Manufacturer Defendant

Purdue

- 62. Purdue promulgated numerous misrepresentations regarding opioids to doctors, other prescribers, and consumers to convince doctors to prescribe and consumers to purchase its opioid products, OxyContin, MS Contin, Butrans, Hysingla ER, Dilaudid, and Dilaudid-HP.
- 63. Purdue claimed that addiction is not caused by drugs and addiction is only triggered in susceptible individuals in Purdue's educational brochure, *Providing Relief*, *Preventing Abuse*.

- 64. Purdue misrepresented that certain telltale signs of addiction were not signs of opioid addiction. Through their sponsorship and distribution of the publication *Responsible Opioid Prescribing*, Purdue falsely stated that certain behaviors, such as demanding or manipulative behavior to obtain opioids, visiting multiple doctors to obtain multiple prescriptions, requesting drugs by name, and hoarding opioids, were not signs of opioid addiction.
- 65. Purdue misrepresented that doctors and patients could effectively screen for addiction risk using the Opioid Risk Tool ("ORT")—a five question, one-minute screening questionnaire that Purdue represented could predict the risk of opioid dependence. This test is not a valid screening tool.
- 66. Purdue spread the false message of "pseudoaddiction" to physicians and consumers. Purdue's Vice President of Health Policy, Dr. J. David Haddox, coined the term pseudoaddiction, which he defined as a "syndrome of abnormal behavior" resulting from "inadequate pain management." Dr. Haddox opined that pseudoaddiction is caused by the "undermedication of pain." In presentations to prescribers, Purdue cited Dr. Haddox's research to support the false and perverse proposition that the proper treatment for pseudoaddiction is "more" opioids.
- 67. Purdue's educational pamphlet, *Providing Relief, Preventing Abuse*, represented that "pseudoaddiction has emerged in the literature to describe the inaccurate interpretation of behaviors in patients who have pain that has not been effectively treated." Addictive behavior, according to Purdue, did not preclude "successful opioid therapy."
- 68. Purdue represented falsely that taking opioids improved a person's quality of life. Purdue sponsored *A Policymaker's Guide to Understanding Pain & Its Management*, a

publication by the American Pain Foundation ("APF"), a front organization supported by Purdue. This publication claimed that "multiple clinical studies" showed that opioids improved daily function, psychological health, and overall quality of life for those suffering from chronic pain.

- 69. Purdue represented that opioids "increase your level of functioning" in the APF publication *Exit Wounds*. The publication further suggested that patients should plan for a "recurrence of pain" by "having a supply of a pain medication on hand."
- 70. Purdue also targeted the elderly through both misrepresentations and omissions to prescribers and consumers. Purdue supported the 2009 *Guidelines for the Pharmacological Management of Persistent Pain in Older Persons*. The Guidelines misrepresented that the risk of addiction was "exceedingly low in older patients with no current or past history of substance abuse."
- 71. Purdue also targeted veterans through both misrepresentations and omissions. In the *Exit Wounds* publication, which was presented as the personal narrative of a single veteran, described opioids as the "gold standard" of pain medications and "often under-used." The publication further stated, "Long experience with opioids shows that people who are not predisposed to addiction are unlikely to become addicted to opioid pain medications." The publication also failed to warn of the dangers of taking benzodiazepines, commonly prescribed for PTSD, with opioids. The publication also encouraged veterans that they "may need to push" doctors "hard" to get their preferred pain treatment.
- 72. Purdue engaged KOLs to make misrepresentations regarding the length of time opioids would be effective against pain to physicians and the public. The KOLs used presentation slides created by Purdue while serving as faculty or speakers at meetings attended

by Florida prescribers to make these misrepresentations. Purdue also instructed its sales representatives to make these same misrepresentations to prescribers.

- 73. The false statements and omissions by Purdue were made to Florida doctors, other prescribers, and consumers and led them to prescribe and consume Purdue's opioid products.
- 74. The statements and/or omissions Purdue made regarding opioids and the risks and benefits of non-opioid pain relief treatments were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Section 817.034, Florida Statutes.

Endo

- 75. Endo misrepresented the risks and benefits of opioids to prescribers and consumers to convince doctors to prescribe and consumers to purchase its opioid products, Percocet, Opana, Opana ER, Percodan, and its generic opioids.
- 76. Endo misrepresented the risk of addiction to opioids on its website www.opana.com. There, Endo represented that "[m]ost doctors who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."
- 77. Further, on its website, www.PainAction.com, Endo misleadingly represented that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them," and, through painknowledge.com, further represented that "[p]eople who take opioids as prescribed usually do not become addicted."
- 78. Endo participated in the distribution of the APF publication *Exit Wounds*, which misrepresented that tolerance to medication and withdrawal symptoms "are not signs of

addiction." Endo also advocated in this publication that denying opioids to a patient with a history of substance abuse was "invalid."

- 79. Endo sponsored and distributed *Responsible Opioid Prescribing*, which falsely claimed demanding or manipulative behavior to obtain opioids and other aberrant behavior are not signs of opioid addiction.
- 80. Endo stated in a brochure to the public, *Understanding Your Pain: Taking Oral Opioid Analgesics*, that (1) "Taking opioids for pain relief is not addiction"; and (2) "Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problem."
- 81. In the same publication, Endo stated that the following test should guide patients in determining whether they are addicted to opioids: "Ask yourself: would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons—to relieve pain and improve your function. You are not addicted."
- 82. Endo misrepresented to prescribers that physical dependence on opioids does not mean that a person is addicted.
- 83. Endo advocated the use of the ORT by patients to predict their risk of opioid addiction.
- 84. Endo also funded and promoted the Screener and Opioid Assessment for Patients with Pain ("SOAPP") as another tool to determine if a person is likely to become addicted to opioids. The Centers for Disease Control and Prevention ("CDC") has debunked the use of both the ORT and SOAPP as unable to accurately predict a patient's risk of opioid addiction.
- 85. Endo trumpeted the false concept of pseudoaddiction. Endo represented that symptoms of addiction could be remedied by prescribing more opioids. Endo distributed

Avoiding Opioid Abuse While Managing Pain by KOL Dr. Lynn Webster that claims a doctor should regard aberrant patient behavior as pseudoaddiction and increase the patient's opioid dose to remedy the situation.

- 86. Endo funded the distribution of *Responsible Opioid Prescribing* (2007). This book states that signs of addiction in patients, such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all mere signs of pseudoaddiction and not addiction.
- 87. Endo told prescribers that pseudoaddiction was drug-seeking behavior that would cease upon effective pain treatment.
- 88. Endo failed to disclose that high doses of opioids posed danger to patients.

 Through front organizations, the APF and National Initiative on Pain Control ("NIPC"), Endo sponsored the website painknowledge.com until 2012. In 2009, the website claimed that opioid dosages should be raised until "you are on the right dose of medication for your pain."
- 89. Endo distributed *Understanding Your Pain: Taking Oral Opioid Analgesics*, a patient-education pamphlet edited by KOL Dr. Russell Portenoy. In the Q&A Section, the pamphlet indicated that a patient will not run out of pain relief but failed to disclose the risks involved with taking high dose opioids.
- 90. Endo instructed its sales representatives to tell prescribers that opioids would improve patients' ability to function, allowing them to return to work and increase physical activity. For example, Endo distributed a flyer to doctors claiming that use of Opana ER would allow a patient with chronic pain to work as a chef.
- 91. The Endo-sponsored website painknowledge.com represented in 2009 that with opioids "your level of function should improve; you may find you are now able to participate in

activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

- 92. Endo sponsored *Responsible Opioid Prescribing*, which stated that patients improved their function with opioids and that functional improvement is the goal of a "long-term therapeutic treatment course."
- 93. In 2012, Endo began touting its reformulated Opana ER as resistant to crushing and less likely to be misused.
- 94. Endo also targeted veterans through both misrepresentations and omissions. Like Purdue, Endo sponsored the APF publication, *Exit Wounds*, which states, "Long experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The publication failed to warn of the dangers of taking benzodiazepines with opioids. The publication advised veterans that they "may need to push" doctors "hard" to get their preferred pain treatment.
- 95. Endo misrepresented the risks and benefits of non-opioid pain relief treatments and omitted material facts about opioids. For example, Endo distributed the case study *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* to prescribers. It described a patient who was using Nonsteroidal Anti-inflammatory Drugs ("NSAIDs") for pain management as having "a massive upper gastrointestinal bleed believed to be related to his protracted use of NSAIDs" over eight years, and used this information as a reason to recommend opioid based pain treatments without disclosing the serious risks of opioid treatments.
- 96. Through APF and NIPC, Endo sponsored and funded the website painknowledge.com through 2012. The website contained a page titled "Pain: Opioid Therapy," which listed certain adverse effects from opioids but omitted the severe adverse effects of

hyperalgesia, immune system and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

- 97. The Endo-sponsored APF publication, *Treatment Options: A Guide for People Living with Pain*, represented that "NSAIDs can cause life-threatening side effects in some persons" and that "[t]here are 10,000 to 20,000 deaths each year because of the side effects of this class of medicines." The publication stated that opioids could be "increased over time" and that there was "no ceiling dose as there is with the NSAIDs," while failing to disclose that opioids pose severe and life-threatening effects and more people die each year from opioid use than from NSAID use.
- 98. The false statements and omissions by Endo were made to Florida doctors, other prescribers, and consumers and led them to prescribe and consume Endo's opioid products.
- 99. The statements and/or omissions Endo made regarding opioids and the risks and benefits of non-opioid pain relief treatments were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it and were made to further a scheme to defraud consumers and prescribers in violation of Section 817.034, Florida Statutes.

<u>Janssen</u>

- 100. Janssen misrepresented the risks and benefits of opioids to prescribers and consumers to convince doctors to prescribe and consumers to purchase its opioid products, Duragesic, Tapentadol IR, Nucynta, and Nucynta ER.
- 101. Janssen misrepresented the risks of developing opioid addiction. Janssen stated to prescribers that their reluctance to prescribe Nucynta was unfounded because the risks were lower than generally believed.

- 102. Janssen misrepresented to prescribers that most patients will not experience withdrawal after ending Nucynta treatment.
- 103. On its website www.prescriberesponsibly.com, Janssen represented that the risks of becoming addicted to opioids are overstated. Furthermore, Janssen stated that "true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid therapy."
- 104. In Finding Relief: Pain Management for Older Adults (2009), Janssen, noting that opioids had been used "for centuries," described the addictive qualities of opioids as a myth: "Many studies show that opioids are rarely addictive when used properly for the management of chronic pain." Janssen claimed some opioids were "less likely to be addictive." The publication disclosed certain minor side effects of opioids, but failed to disclose the material risks of abuse and addiction.
- 105. Through its sales representatives, Janssen represented to prescribing doctors that Nucynta's formulation had properties that curtailed addiction risks relative to other opioids.
- 106. A Janssen speaker presentation titled *A New Perspective for Moderate to Severe Pain Relief: A Focus on the Balance of Efficacy and Tolerability*, created in March 2011, listed the negative side effects of Nucynta but failed to include the risks of abuse or addiction.
- 107. Janssen also promoted the use of the ORT as a valid way to determine whether a patient is likely to become addicted to opioids, even though the ORT has been discredited as an invalid test.
- 108. Janssen stated publicly that the risk of addiction to opioids "can usually be managed" by opioid agreements between doctors and patients, which purported to set forth opioid usage plans for patients.

- 109. Like other Manufacturer Defendants, Janssen promoted the fake concept of pseudoaddiction. From 2009 to 2011, Janssen, through the APF's website, "Let's Talk Pain," stated falsely that "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated" and that "[p]seudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."
- 110. Janssen, through publications, speaker presentations, and sales personnel falsely represented that high doses of opioids posed little danger to patients.
- 111. In Finding Relief: Pain Management for Older Adults (2009), Janssen mischaracterized dose limitations as "disadvantages" of alternative pain management medications. Janssen also failed to disclose the risks associated with increasing opioid dosages.
- 112. Janssen misrepresented that opioids create positive long-term outcomes for users with chronic pain. For example, Janssen sponsored a patient education guide titled *Finding Relief: Pain Management for Older Adults (2009)*, which was distributed by its sales force. It featured a man playing golf on the cover and listed examples of expected functional improvement from opioids, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It stated that "opioids may make it easier for people to live normally."
- 113. Janssen advertised that "opioid efficacy meets unexpected tolerability" in patients with end-stage degenerative osteoarthritis of the hip or knee. Janssen claimed that taking Nucynta was appropriate to address long-term, chronic pain even though the claim was based on a study conducted over only five days.
- 114. Janssen promoted Nucynta as crush and breakage resistant to persuade prescribers that Nucynta was less likely to be abused.

- 115. Janssen co-sponsored the APF publication *Special Considerations: Pain in Specific Populations*. This publication sought to normalize opioid use as a treatment option among the elderly.
- 116. Janssen sponsored the APF publication, *Exit Wounds*, which states, "Long experience with opioids shows that . . . people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications." The publication failed to warn of the dangers of taking benzodiazepines with opioids. The publication advised veterans that they "may need to push" doctors "hard" to get their preferred pain treatment.
- 117. The false statements and omissions by Janssen were made to Florida doctors, other prescribers, and consumers and led them to prescribe and consume Janssen's opioid products.
- 118. The statements and/or omissions Janssen made regarding opioids and the risks and benefits of non-opioid pain relief treatments were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Section 817.034, Florida Statutes.

Cephalon

- 119. Cephalon misrepresented the risks and benefits of opioids to prescribers and consumers to convince doctors to prescribe and consumers to purchase its opioid products, Actiq and Fentora.
- 120. Cephalon misrepresented the risk of addiction to opioids. For example, Cephalon co-sponsored the APF publication *Treatment Options: A Guide for People Living with Pain* (2007), which noted it was unfortunate that law enforcement referred to opioids as "narcotics"

because use of this phrase "reinforces myths and misunderstandings as it places emphasis on potential abuse rather than on the importance of their use as pain medicines." The publication also dismissed the concern that an "average person" could become addicted to opioids and blamed this concern for doctors' hesitation to write opioid prescriptions.

- 121. Cephalon sponsored and helped create *Opioid Medications and REMS: A Patient's Guide*, a guidebook that misrepresented the risks of addiction to opioids. The guidebook represented that patients without a history of addiction are not likely to become addicted to opioids. Cephalon circulated the guidebook nationally, and it was available to and intended to reach prescribers in Florida.
- 122. Cephalon's sales representatives frequently failed to disclose the risks of opioid usage, including addiction, when communicating with prescribers as well as failing to disclose other material risks associated with opioid use, including risk of overdose, respiratory depression, hyperalgesia, hormonal dysfunction, neonatal abstinence syndrome, decline in immune function, confusion, dizziness (and increased falls and fractures in the elderly), and potentially fatal interactions with alcohol or benzodiazepines.
- 123. Cephalon advanced the phony concept of pseudoaddiction. In a brochure entitled Making Pain Talk Painless: A Guide to Help You Talk with Your Doctor about Pain Management, Cephalon stated that medicine-seeking behavior is not addiction and encouraged patients to talk to their doctor about obtaining more pain medicine.
- 124. Cephalon misrepresented that taking opioids for chronic long-term pain provided a patient with improved quality of life. For example, Cephalon, through the APF, sponsored *Treatment Options: A Guide for People Living with Pain (2007)*, which was written for patients and claimed that opioid drugs could give them "a quality of life [they] deserve." The publication

further represented that despite the "great benefits of opioids, they are often under-used" because providers and patients may be fearful of them.

- Pain, which promoted opioids for unsafe uses and misleadingly portrayed the risks and benefits of using opioids for the treatment of chronic pain. The CME misrepresented that Actiq and Fentora, taken in conjunction with long-acting opioids, would help patients regain functionality, improve patients' quality of life, and allow for a more active lifestyle. *Optimizing Opioid Treatment for Breakthrough Pain* was available online and reached Florida prescribers.
- 126. Cephalon's opioid products, Actiq and Fentora, have been demonstrated to be medically safe and appropriate for use in treating breakthrough cancer pain for those patients who are already opioid tolerant. Breakthrough cancer pain is an acute, short-term onset of pain, of moderate-to-severe intensity, affecting patients whose pain is otherwise stable.
- 127. Fentanyl, an ingredient in Actiq and Fentora, is linked to fatal respiratory complications in patients.
- 128. Because of the dangers of Actiq and Fentora, objective literature, studies, and other pertinent medical community knowledge established that these products must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq and Fentora are contraindicated in the management of acute or postoperative pain.
- 129. However, Cephalon aggressively marketed its opioid products for "breakthrough pain," a term created by Cephalon to encourage improper prescriptions and use of the products.

 Specifically, Cephalon actively marketed and promoted Actiq for treatment of non-cancer pain.

Cephalon also represented that Actiq was appropriate for a variety of conditions, including sports injuries, headaches, and back pain.

- 130. Cephalon executive Bob Roche boasted in 2007 that the launch of Fentora had been aggressive and the company sought to expand the use of Fentora to broader indications, including lower back pain and breakthrough neuropathic pain.
- 131. On September 10, 2007, Cephalon informed doctors that Fentora may lead to death and other "serious adverse events." Cephalon stated, "These deaths occurred as a result of improper patient selection (e.g., use in opioid non-tolerant patients), improper dosing, and/or improper product substitution." Cephalon's warning to doctors omitted any reference to Cephalon's deliberate and knowing role in "improper patient selection."
- 132. Cephalon nonetheless continued to promote Fentora for use by all cancer patients, regardless of whether the patient was opioid tolerant.
- 133. Cephalon created a marketing plan to spread its misinformation. This campaign was intended to, and did, reach a nationwide audience of prescribers, including those in Florida. Cephalon spent millions of dollars to promote its opioid products.
- 134. Cephalon was aware that physicians were prescribing Fentora for uses that were not medically supported as safe and appropriate. Cephalon was also aware that its fraudulent marketing practices impacted prescription rates.
- 135. In 2011, Cephalon wrote and copyrighted an article titled 2011 Special Report:

 An Integrated Risk Evaluation and Risk Mitigation Strategy for Fentanyl Buccal Tablet

 (FENTORA®) and Oral Transmucosal Fentanyl Citrate (ACTIQ®) that was published in Pain

 Medicine News. The article promoted use of Cephalon's drugs by representing that the

 "judicious use of opioids can facilitate effective and safe management of chronic pain" and that

Fentora had "been shown to be effective in treatment of [breakthrough pain] associated with multiple causes of pain."

- Breakthrough Pain, which was authored by KOL Dr. Perry Fine and distributed by Pain

 Medicine News in 2009. The CME represented, "Clinically, broad classification of pain

 syndromes as either cancer- or noncancer-related has limited utility." The CME concluded, "All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial of opioid therapy"
- 137. The false statements and omissions by Cephalon were made to Florida doctors, prescribers, and consumers and led them to prescribe and consume Cephalon's opioid products.
- 138. The statements and/or omissions Cephalon made regarding opioids and the risks and benefits of non-opioid pain relief treatments were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Section 817.034, Florida Statutes.

Allergan

- 139. Allergan misrepresented the risks and benefits of opioids to prescribers and consumers to convince doctors to prescribe and consumers to purchase its opioid products, Kadian and Norco, as well as its generic versions of Kadian, Duragesic, and Opana.
- 140. Allergan distributed a brochure representing to patients that the risk of addiction to opioids was "less likely if you never had an addiction problem," implying the risk of addiction was low.

- 141. Allergan misrepresented that doctors and patients could effectively screen for addiction by using the invalid ORT. Allergan told prescribers that risk-screening tools reduced patients' chances of addiction to opioids.
- 142. Allergan told prescribers that opioids pose little addiction risk when taken by patients who have no history of addiction or abuse.
- 143. On information and belief, Allergan promoted the use of "opioid agreements" between doctors and patients, which purported to set forth opioid usage plans for patients as a way to reduce the likelihood of addiction. However, the CDC and prevailing medical literature have shown that opioid agreements are not effective at preventing opioid addiction.
- 144. Allergan claimed to prescribers that opioids improve function, opioid patients have a low risk of addiction, many opioid patients are merely experiencing pseudoaddiction, and opioid withdrawal is a minor concern.
- 145. Allergan misrepresented the dangers of high-dose opioid treatment. Allergan told prescribers that pain patients would not develop opioid tolerance and opioid prescriptions had no dosage ceiling and were therefore safe.
- 146. On information and belief, Allergan misrepresented the risks of increasing patients' doses of opioids. Allergan told doctors to begin a patient on a low dose and then titrate the patient to increasingly higher doses until the patient experiences adequate relief. Allergan instructed doctors to set dosage levels based on the needs of the patient with no maximum dose in mind.
- 147. Allergan also misrepresented that opioids create positive long-term outcomes for users with chronic pain.

- 148. Allergan misrepresented to prescribers that patients taking opioids for chronic pain have improved functionality if they continue taking opioids.
- 149. Allergan misrepresented the risks and benefits of non-opioid treatments while omitting material facts about opioids. On information and belief, Allergan falsely represented to prescribers that opioids were safer than other drugs with dose ceilings, such as NSAIDs and acetaminophen, because opioids do not have dose ceilings.
- 150. Allergan represented to doctors that it was safer for a patient to take opioids for pain maintenance than other pain medications, such as NSAIDs, in older patients.
- 151. The false statements and omissions by Allergan were made to Florida doctors, prescribers, and consumers and led them to prescribe and consume Allergan's opioid products.
- 152. The statements and/or omissions Allergan made regarding opioids and the risks and benefits of non-opioid pain relief treatments were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Section 817.034, Florida Statutes.

E. The Manufacturer Defendants Used Front Organizations to Promote Misrepresentations about Opioids.

- 153. The Manufacturer Defendants used front organizations, which were funded, controlled, or operated by the Manufacturer Defendants, to communicate with doctors, other prescribers, and consumers about using opioids for chronic pain treatment.
- 154. These front organizations include the APF, the American Academy of Pain Medicine ("AAPM"), the AGS, the Pain Care Forum ("PCF"), a forum of the APF, the American Pain Society ("APS"), and the NIPC, among others. These front organizations purposely appeared as though they were acting independently of the Manufacturer Defendants.

- 155. The Manufacturer Defendants funded and used these front organizations as mouthpieces to promote the widespread use of opioids for chronic pain, which benefited the sales of the Manufacturer Defendants' opioid products. The use of these front organizations appeared to skirt applicable law that restricts the information the Manufacturer Defendants may convey about their products. In fact, the AAPM and APS issued guidelines in 2009 recommending the use of opioids to treat chronic pain.
- 156. The APF received more than \$10 million of funding from the Manufacturer Defendants and other opioid manufacturers during its existence from 2007 to 2012. The misrepresentations by the Manufacturer Defendants through the APF continued beyond 2012 to this day. Endo paid the APF more than \$1 million in 2010, over half of the APF's funding that year. Janssen also contributed substantially to the APF.
- 157. The Manufacturer Defendants, through the AGS, targeted the elderly by making false representations to prescribers and consumers. The AGS published *Pharmacological Management of Persistent Pain in Older Persons*, which parroted the Guidelines' false representation that the risk of addiction was "exceedingly low in older patients with no current or past history of substance abuse."
- 158. Purdue, Janssen, and Endo participated in the production and dissemination of two publications known as "Guidelines" from the AGS entitled *The Management of Persistent Pain in Older Persons*, and in 2009, published *Pharmacological Management of Persistent Pain in Older Persons*. The AGS contracted with at least Purdue to sponsor CMEs based upon these Guidelines.
- 159. The AAPM maintained a corporate relations council whose members paid \$25,000 per year, in addition to other funding. Purdue, Endo, Cephalon, and Allergan served as

members of the AAPM corporate relations council and paid the yearly fee. In 2011 alone, the AAPM received \$1.3 million from pharmaceutical companies.

- 160. The AAPM and APS issued guidelines in 2009 ("AAPM/APS Guidelines") recommending the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine, received support from Janssen and Cephalon.
- 161. On information and belief, Purdue, Endo, Cephalon, and Allergan presented deceptive programs to doctors who attended AAPM's annual meeting.
- 162. The front organizations were successful in spreading the Manufacturer Defendants' messages about opioids. The APF's messages regarding pain treatment have reached millions of people. The Manufacturer Defendants' false messages through the front organizations have continued to this day.

F. The Manufacturer Defendants Used Key Opinion Leaders to Promote Misrepresentations about Opioids.

- 163. Defendants Purdue, Endo, and Janssen employed KOLs to tout the benefits of opioid treatment for chronic pain in books, medical literature, pamphlets, speeches, research studies, and treatment guidelines. The KOLs also gave speeches and presented CMEs touting the benefits of opioids for chronic pain while omitting the severe risks of opioid treatment. The KOLs served as consultants for Purdue, Endo, and Janssen. Additionally, the KOLs served as members of Purdue and Endo's advisory boards.
- 164. The KOLs included Dr. Lynn Webster and Dr. Russell Portenoy. Dr. Webster developed the ORT, which the Manufacturer Defendants represented could predict the risk of opioid dependence. Janssen placed Dr. Webster's ORT on Janssen's website and endorsed its use.

- 165. The KOLs also advocated for the benefits of so-called abuse and tamper resistant opioid formulations sold by the Manufacturer Defendants.
- 166. The Manufacturer Defendants pushed their sales representatives to use the work of KOLs, such as Dr. Russell Portenoy, to persuade doctors to prescribe opioids liberally.
- 167. The KOLs furthered the Manufacturer Defendants' scheme to increase the number of opioid prescriptions and opioid use by consumers in Florida and elsewhere.

G. The Distributor Defendants Caused a Flood of Opioids to Engulf Florida.

- 168. The Distributor Defendants have a duty under Florida law to prevent the diversion of opioids for non-legitimate, non-medical purposes. Given their role handling most of the opioids in this country, the Distributor Defendants are expected to provide a vital safeguard against the diversion of opioids into illegal, non-medical channels.
- 169. The Distributor Defendants have unconscionably violated their duty by shipping hundreds of millions of opioids into Florida without sounding the alarm or stopping the shipments.
- 170. The quantity of opioids distributed in Florida far exceeds the medical need of Florida and its communities.
- 171. The Distributor Defendants knew that their customers in Florida were ordering an inordinately high number of opioids.
- 172. The Distributor Defendants refused to report the suspicious opioid ordering activities of numerous Florida pharmacies.
- 173. The Distributor Defendants failed to properly assess their customers to determine whether their customers' orders of opioids were valid.
 - 174. The Distributor Defendants also continued to fill the suspicious opioid orders

from their Florida customers.

- 175. The Distributor Defendants have repeatedly been sanctioned for their failure to monitor suspicious ordering of opioids, continuing to fill suspicious orders of opioids, and their failure to report suspicious orders of opioids in Florida and elsewhere.
- 176. The Defendants knew that widespread diversion of oxycodone pills and other opioids in Florida had occurred and that Defendants needed to put controls in place to stop the diversion of oxycodone and other opioids in Florida.
- 177. On information and belief, the Defendants failed to put controls in place and allowed diversion of oxycodone and other opioids to continue in Florida.
- 178. For example, AmerisourceBergen violated its duties under Florida law and continually allowed diversion of opioids to occur at its Orlando, Florida facility.
- 179. Cardinal violated its duties under Florida law and continually allowed diversion of opioids to occur in Florida, including the diversion of hydrocodone at its Lakeland facility.
- 180. McKesson violated its duties under Florida law and continually allowed diversion of opioids to occur in Florida, including the diversion of hydrocodone at its Lakeland facility.
- 181. Mallinckrodt violated its duties under Florida law and continually allowed diversion of opioids to occur in Florida, including the diversion of oxycodone.
- 182. The Distributor Defendants failed to conduct due diligence to understand the normal and expected transactions by their customers.
- 183. The Distributor Defendants failed to establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions of opioids.
- 184. The Distributor Defendants neglected to monitor and identify suspicious orders of opioids by their customers.

- 185. The Distributor Defendants failed to report to the State of Florida suspicious orders of opioids from their customers in Florida.
- 186. The Distributor Defendants continued to fill suspicious orders of opioids by their customers in Florida.
- 187. The Distributor Defendants' conduct violates Section 499.0121, Florida Statutes, which imposes obligations upon distributors including knowing their customers, identifying suspicious orders, assessing large orders in the context of the community, preventing suspicious transactions, and reporting unusually large or otherwise questionable transactions.
- 188. The Distributor Defendants' failure to report, monitor, detect, investigate, and refuse to fill suspicious orders of opioids is a direct and proximate cause of, and/or substantial factor contributing to, the diversion of prescription opioids into Florida for consumption for non-medical, non-scientific purposes.
- 189. The Distributor Defendants knew that widespread diversion of opioids was occurring in Florida, but turned a blind eye to this activity in order to earn higher profits.
- 190. The Distributor Defendants' conduct led to precisely the harm that Florida law was designed to prevent.
- 191. The Distributor Defendants' unlawful diversion of opioids is a direct and proximate cause of and/or a substantial factor leading to opioid abuse, addiction, morbidity, and mortality in Florida.
- 192. The Distributor Defendants' unlawful diversion of opioids is a direct and proximate cause of and/or a substantial factor leading to the opioid epidemic and all the past and ongoing damages incurred by the State of Florida.

- H. The Distributor Defendants Marketed the Manufacturer Defendants' Opioid Products Even Though the Distributor Defendants Knew About Widespread Diversion of Opioids and that a High Number of Opioids Were Already Being Ordered by Their Customers in Florida.
- 193. The Distributor Defendants marketed both branded and generic opioids to pharmacies and, in some cases, health care providers and patients.
- 194. The Distributor Defendants were paid by the Manufacturer Defendants for their promotion of opioids.
- 195. Typically, the Manufacturer Defendants provided the ads for the opioid product to be marketed, and the Distributor Defendants provided the platform for the marketing via websites, telemarketing, faxes, and brochures.
- 196. For example, McKesson assisted Purdue with the marketing of one of its opioid products as part of McKesson's Pharmacy Intervention Program.
 - 197. McKesson and Cardinal promoted opioids for Allergan.
 - 198. Cardinal offered to market Fentanyl for one Manufacturer Defendant.
- 199. McKesson, Cardinal, and AmerisourceBergen all assisted with the marketing of one of Janssen's opioid products.
- 200. In addition, McKesson offered to provide behavioral coaching services for the Manufacturer Defendants. If a Manufacturer Defendant hired McKesson, then one of McKesson's call center staff trained in behavioral coaching techniques would contact patients directly by telephone to ensure that patients took their medications. On information and belief, McKesson provided behavioral coaching services to the Manufacturer Defendants for their opioid products.
- 201. McKesson ran Behavioral Call Campaigns ("BCCs") where McKesson's staff called patients directly to promote adherence to the dosing regimen for specific drugs. On

information and belief, McKesson conducted BCCs for the Manufacturer Defendants to promote their opioid products.

- 202. As part of its promotional program, McKesson studied the impact of its coaching services on the length of time that patients take specific drugs. McKesson boasted that its coaching services caused patients to be 25% more adherent to their medications, which according to McKesson, translated to an additional 31 days of taking specific medications. On information and belief, McKesson's coaching services caused patients to take more of the Manufacturer Defendants' opioid products.
- 203. Cardinal advertised to the Manufacturer Defendants the availability of Cardinal's promotional services. If hired by a Manufacturer Defendant, Cardinal would provide a variety of services to enable the Manufacturer Defendant to reach physicians with specific specialties.
- 204. Cardinal's promotional services offered to the Manufacturer Defendants included programs to train KOLs. Cardinal also offered to provide KOLs to deliver web-based conference programs promoting a drug manufacturer's products. Further, Cardinal offered a proprietary database of providers to whom the Manufacturer Defendants could send email blasts and presentation material to promote its products. On information and belief, Cardinal provided these services to the Manufacturer Defendants to promote opioids sold by the Manufacturer Defendants.
- 205. On information and belief, Cardinal sent thousands of emails to pharmacists to promote at least two Manufacturer Defendants' opioid products.
- 206. AmerisourceBergen broadly advertised to the Manufacturer Defendants the availability of AmerisourceBergen's promotional services. If hired by a Manufacturer Defendant, AmerisourceBergen provided targeted communications to customers through a

variety of marketing media to distinguish the Manufacturer Defendant's product. On information and belief, AmerisourceBergen provided these services to the Manufacturer Defendants for the promotion of the Manufacturer Defendants' opioid products.

- 207. On information and belief, AmerisourceBergen promoted at least three Manufacturer Defendants' opioid products.
- 208. The Distributor Defendants also provided discount cards to induce consumers to purchase the Manufacturer Defendants' opioids.
- 209. For example, McKesson has administered Purdue's prescription savings card program for OxyContin, Butrans, and Hysingla.
 - 210. Mallinckrodt also actively marketed opioid products.
- 211. The Distributor Defendants engaged in marketing efforts for the Manufacturer Defendants despite knowing about high order histories and widespread diversion of these same opioids by their customers in Florida and elsewhere.
- 212. On information and belief, the Distributor Defendants continually engaged in marketing efforts for the Manufacturer Defendants for at least the past ten years.
 - I. The Applicable Statutes of Limitation Are Tolled Because of the Defendants' Fraudulent Concealment and Public Misrepresentations.
- 213. The State of Florida's claims against the Defendants are subject to the doctrines of equitable estoppel and equitable tolling. The Defendants have knowingly and fraudulently concealed the facts supporting the allegations alleged in this Complaint. The State of Florida has been unable to access information sufficient to discover and properly bring claims against the Defendants.
- 214. Consequently, the Defendants may not raise statute of limitations defenses. The Defendants purposefully concealed their conduct.

- 215. The Distributor Defendants made public misrepresentations that suggested that the Distributor Defendants were taking adequate efforts to comply with the requirements of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, including representations that they were implementing suspicious order monitoring programs in governmental settlements. Thus, any applicable statutes of limitation are tolled. Florida did not know, and could not have known, many key facts relevant to bringing this Complaint until shortly before this Complaint was filed.
- 216. The Defendants' misrepresentations led the public to believe that the Defendants were working to fight the opioid epidemic.
- 217. Furthermore, through their participation in trade organizations, the Healthcare Distribution Management Association ("HDMA")⁵ and the NACDS, the Distributor Defendants made the following statements in an amicus brief in *Masters Pharmaceuticals*,⁶ which state the Distributor Defendants were acting in accordance with applicable law:
 - a. HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.
 - b. Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.
 - c. A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.
 - d. Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash.

In 2016, the HDMA changed its name to the Healthcare Distribution Alliance.

⁶ Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Administration, Case No. 15-1335, 2016 WL 1321983 (D.C. Cir. Apr. 4, 2016).

- 218. The above statements imply that the Distributor Defendants took responsibility for and acted in complete accordance with Florida law with respect to distributing controlled substances. Taken together with the Distributor Defendants' other statements in legal matters and the media, the Distributor Defendants have demonstrated actual or constructive knowledge that these statements were made to mislead the public that the Distributor Defendants were not in dereliction of their duties.
- 219. The State of Florida reasonably relied on the Distributor Defendants' statements regarding their supposed compliance with Florida law.
- 220. Further, the Manufacturer Defendants employed KOLs and funded front organizations to promote falsely the health benefits of opioids and conceal the reality of the harmfulness and highly addictive nature of the opioids the Manufacturer Defendants promoted, advertised, and sold in Florida.
- 221. Therefore, the Defendants cannot claim prejudice from the tolling of the State of Florida's claims. The State of Florida filed suit promptly upon discovering facts sufficient to show a cause of action. The Defendants knowingly concealed these same facts.
- 222. Florida otherwise reasonably relied on the Defendants' statements that the Defendants had acted in full accordance with Florida law. Consequently, Florida's claims were equitably tolled until Florida discovered the Defendants' conduct before filing this Complaint. The Defendants are estopped from asserting a statute of limitations defense because they took affirmative steps to fraudulently conceal their own conduct.
 - J. Defendants' Conduct Has Injured the State of Florida and Its Citizens.
- 223. Opioids became a common treatment for chronic pain because of the Manufacturer Defendants' campaign of misrepresentations. The Distributor Defendants'

conduct has contributed to the illegal diversion of opioids in Florida and fueled an illegal market for opioids. As a result, opioid usage rates—and opioid abuse rates—have skyrocketed in Florida and in the United States. Between 1999 and 2014, sales of opioids nearly quadrupled, according to the CDC. Nearly 259 million opioid prescriptions were written in the United States in 2012 alone. This equates to more than one opioid prescription for every American adult. At the same time, diagnoses of opioid addiction increased nearly 500% from 2010 to 2016. Many tens of thousands of Floridians are currently addicted to opioids.

- 224. Opioid users often resort to heroin when they run out of opioids. Heroin is cheaper and more readily available. According to the National Survey on Drug Use and Health, four out of five current heroin users report that their drug use began with an opioid pain reliever.
- 225. There were nearly 13,000 deaths due to heroin overdoses in the United States in 2015, and 779 of those occurred in Florida. Pasco County has experienced an uptick in heroin-related deaths, and other counties in Florida have also experienced heroin-related deaths.⁷
- 226. Deaths from opioid overdoses do not fully capture the breadth of the damages suffered by Florida citizens. Opioid use results in thousands of hospitalizations and emergency room visits as well. For example, in 2014, there were 21,700 opioid-related emergency department visits. In Miami-Dade County alone, there were 128 hospital admissions for opioid poisoning in 2015. The State of Florida often bears the cost of treatment.
- 227. Another result of Defendants' actions is the upsurge of the sober home crisis in Florida. The opioid epidemic has created a market of thousands of people with opioid dependence. Instead of helping those with addiction problems recover, many sober homes have

⁷ Jones, C.M., Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers- United States, 2002-2004 and 2008-2010. Drug Alcohol Depend. 2013 Sep 1; 132(1-2): 95-100. doi: 10.1016/j.drugalcdep.2013.01.007/ Epub 2013 Feb 12

become hotbeds of opioid distribution and have distorted the character of once-peaceful neighborhoods.

- 228. The opioid crisis has impacted some of Florida's most vulnerable demographics, such as the elderly. The AARP reports that elderly Americans have faced a 500% increase in hospitalization rates related to opioids over the last twenty years. In 2015, "physicians prescribed opioid painkillers to almost one-third of all Medicare patients, or nearly 12 million people. In the same year, 2.7 million Americans over age 50 took painkillers in amounts—or for reasons—beyond what their physicians prescribed."
- 229. The Defendants' actions alleged in this Complaint have caused numerous societal injuries to the State of Florida. The Defendants' conduct has contributed to deaths, drug addiction, personal injuries, child neglect, children placed in foster care, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment, and lost productivity, among others. The State of Florida is expending its resources to address these and other social problems resulting from the opioid crisis and will continue to expend resources addressing these problems.
- 230. The Defendants' actions alleged in this Complaint have caused numerous economic injuries to the State of Florida. The Defendants' conduct has caused economic losses for medical treatment, rehabilitation costs, hospital stays, emergency room visits, emergency personnel costs, law enforcement costs, substance abuse prevention costs, costs for displaced children, naloxone costs, medical examiner expenses, self-funded state insurance costs, and lost tax revenues, among others.
- 231. The societal and economic injuries incurred by the State of Florida were foreseeable by the Defendants.

232. The Defendants' conduct was the proximate cause of the harm suffered by the State of Florida.

Count I <u>Violation of the Florida Deceptive and Unfair Trade Practices Act</u> (All Defendants)

- 233. This an action against all Defendants for violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").
- 234. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.
- 235. Defendants' acts or practices alleged herein are unfair, deceptive, and/or unconscionable in violation of FDUTPA, § 501.201, *et seq.*, Florida Statutes.
- 236. Defendants' sale, promotion, marketing, advertising, distribution, and manufacturing of opioid products in the State of Florida involves trade or commerce within the meaning of FDUTPA.
- 237. Defendants sold, promoted, marketed, distributed, and advertised opioid products to the State of Florida and its governmental entities, businesses, and consumers within Florida.
- 238. The Manufacturer Defendants' misrepresentations and omissions of material facts, as detailed above, constitute deceptive trade practices that are prohibited by FDUTPA.
- 239. The Distributor Defendants' actions in the distribution of opioids, as detailed above, constitute unfair acts and/or unconscionable acts or practices that are prohibited by FDUTPA. The Distributor Defendants' acts or practices offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.

- 240. The Distributor Defendants' multiple acts of marketing the Manufacturer Defendants' opioid products to the Distributor Defendants' customers that the Distributor Defendants knew or should have known were engaged in the diversion of opioids constitute unfair acts and/or unconscionable acts or practices that are prohibited by FDUTPA. The Distributor Defendants' acts or practices offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses, and consumers.
- 241. Defendants' unfair, deceptive, and unconscionable acts or practices, or the effects thereof, are continuing, will continue, and are likely to recur unless permanently restrained and enjoined.
- 242. Further, a FDUTPA violation also occurs when a Defendant violates "any law, statute, rule, regulation, or ordinance which proscribes unfair methods of competition, or unfair, deceptive, or unconscionable acts or practices."
- 243. The Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, regulates the trade practices of wholesale drug distributors.
- 244. The Florida Drug and Cosmetic Act requires each Distributor Defendant to "take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature" and to "establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions." Fla. Stat. § 499.0121(15)(3)(b). The Distributor Defendants violated these statutory provisions over a period of at least the past decade while thousands of Floridians became addicted to opioids and died. These violations offend established public policy and are immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental

entities, businesses, and consumers.

- 245. The Distributor Defendants continued to fill suspicious orders of opioids by their customers in Florida. This also constitutes a violation of the Florida Drug and Cosmetic Act and is an unconscionable and/or unfair act or practice. This conduct offends established public policy and is immoral, unethical, oppressive, unscrupulous, or substantially injurious to Florida governmental entities, businesses and consumers.
- 246. Consequently, the State of Florida seeks all available relief under FDUTPA, including but not limited to damages, disgorgement, restitution, civil penalties, equitable relief, injunctive relief, and attorneys' fees and costs.

Count II <u>Violation of the Florida Racketeer Influenced and Corrupt Organization Act</u> (All Defendants)

- 247. This is an action against all Defendants for violation of the Florida Racketeer Influenced and Corrupt Organization Act.
- 248. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.
- 249. This is a claim brought by the State of Florida by and through its Department of Legal Affairs against all Defendants for treble damages, forfeiture, equitable relief, penalties, and attorneys' fees and costs under Chapter 895, Florida Statutes.
- 250. The Department of Legal Affairs is an investigative agency under § 895.02(6), Florida Statutes.
- 251. The Department of Legal Affairs is authorized to institute a civil action under § 895.05(5), Florida Statutes.
 - 252. Defendants' acts and practices as described above constitute violations of

- § 895.03(3), Florida Statutes. Defendants are associated with an enterprise (the "Enterprise") and conducted or participated, directly or indirectly, in such Enterprise through a pattern of racketeering activity. Further, Defendants' acts and practices described above constitute a violation of § 895.03(4), Florida Statutes, because the Defendants conspired or endeavored to violate § 895.03(3), Florida Statutes.
- 253. The Enterprise consists of the Manufacturer Defendants, the front organizations they supported, the Distributor Defendants, and the KOLs supported by the Manufacturer Defendants. The Enterprise is ongoing and continuing and ensures the continuing overprescription and flow of opioids to Florida residents.
- 254. The Manufacturer Defendants, front organizations, and KOLs participated in the Enterprise by sharing a common purpose of marketing opioids for chronic pain through numerous violations of Fla. Stat. § 817.034. They knowingly made false and misleading statements or knowingly omitted material statements to Florida physicians, other prescribers, consumers, the State of Florida, and the general public in furtherance of the fraudulent scheme.
- 255. The Manufacturer Defendants participated in the Enterprise through a pattern of racketeering activity. The Manufacturer Defendants performed thousands of acts in violation of Fla. Stat. § 817.034. The last act was conducted within five years, and at least one other act was conducted within the last ten years preceding the filing of this Complaint. The Manufacturer Defendants willfully and intentionally disseminated misleading and false statements and willfully and intentionally omitted material statements to Florida physicians, other Florida prescribers, Florida consumers, the State of Florida, and the general public. The Manufacturer Defendants did so individually and through front organizations and KOLs, among other means. Florida physicians, other prescribers, consumers, the State of Florida, and the general public

reasonably relied on these representations or omissions of material facts. Acts violating Chapter 817, Florida Statutes, are predicate acts under § 895.02, Florida Statutes.

- 256. By jointly supporting the same front organizations and providing them with false information regarding the prescribing and use of opioids, the Manufacturer Defendants conspired or jointly endeavored to violate § 895.03(3), Florida Statutes, in violation of § 893.03(4), Florida Statutes, with front organizations and KOLs. The Distributor Defendants willfully and knowingly joined this conspiracy by agreeing with Manufacturer Defendants to market their branded and generic opioids in return for payments from the Manufacturer Defendants. The Manufacturer Defendants and Distributor Defendants came to a mutual understanding to try to accomplish a common and unlawful plan to engage in a pattern of racketeering activity as described in this Complaint as did the front organizations and the KOLs.
- 257. The impact of Defendants' fraudulent scheme to market opioids in Florida is still in place as opioids are still being prescribed and consumed for improper uses. The opioid epidemic continues to devastate Florida's health care and law enforcement systems.
- 258. Upon information and belief, all Defendants, in the course of participating in the Enterprise through a pattern of violations of the Florida Communications Fraud Act, § 817.034, Florida Statutes, utilized property, both real and personal, both tangible and intangible, including money, that was used in the course of, intended for use in the course of, derived from, or realized through conduct in violation of ss. 895.01-895.05 while conducting business in Florida. That property is subject to civil forfeiture to the State of Florida. A more particular description of the property to be forfeited is unavailable to the State of Florida at this time.
- 259. The State of Florida and its agencies and instrumentalities have suffered damages from Defendant's violations of the Florida Racketeer Influenced and Corrupt Organization Act.

Accordingly, the State of Florida seeks damages from the Defendants, including treble damages as allowed by law.

Count III Public Nuisance (All Defendants)

- 260. This is an action against all Defendants under Florida common law for damages and abatement of the ongoing public nuisance created by the Defendants.
- 261. Plaintiff adopts, realleges, and incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.
- 262. The State of Florida alleges violations of Florida common law and Section 823.01, *et seq.*, Florida Statutes, and, acting on its own behalf and on behalf of its residents, seeks monetary relief and abatement of the ongoing public nuisance created by Defendants.
- 263. A public nuisance is defined as any annoyance to the community or harm to public health.
- 264. The Defendants have created an opioid epidemic—which constitutes a public nuisance—that has caused enormous public harm in Florida and continues to jeopardize the health and safety of Florida residents.
- 265. The public nuisance created by the Defendants' conduct violates rights common to the Florida public; subverts public order, decency or morals; and causes inconvenience or damage to the public in general. The Defendants' conduct has harmed public health in Florida and is an annoyance to Florida communities.
- 266. Throughout the State of Florida, the Defendants' conduct has affected, and continues to affect, communities and a considerable number of people. The Defendants have caused widespread opioid abuse, addiction, overdoses, injury, crime, and mortality in Florida.

- 267. The Defendants' conduct has injuriously affected public rights, including the right to public health, safety, peace, comfort, and convenience, in communities throughout Florida.
- 268. The public nuisance created by the Defendants has imposed severe economic costs on the State of Florida, its residents, and its communities. The State of Florida, acting on its own behalf and on behalf of its residents, therefore seeks monetary relief from the Defendants.
- 269. Each Defendant created or assisted in the creation of the epidemic of opioid use and injury, and each Defendant is jointly and severally liable for abating it. Left unabated, the opioid epidemic will continue to threaten the health and safety of Florida residents. The State of Florida, acting on its own behalf and on behalf of its residents, therefore seeks monetary and injunctive relief to abate the public nuisance and halt the threat of future harm.

Count IV Negligence (Distributor Defendants)

- 270. This is an action against the Distributor Defendants under Florida common law for negligence.
- 271. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.
- 272. The Office of the Attorney General is entitled to bring claims at common law as the public interest requires and retains wide discretion in making the determination as to the public interest.
- 273. Each Distributor Defendant had carefully-crafted, explicit state-law duties to exercise appropriate care in distributing opioid drugs in Florida.
 - 274. The Distributor Defendants owed duties to Plaintiff State of Florida. Each

Distributor Defendant has duties to protect against the potential diversion of opioids. The Distributor Defendants' duties were assumed voluntarily, as a condition for the privilege of selling controlled substances in Florida. The Distributor Defendants are to guard against the diversion of opioids into non-medical or non-scientific channels.

- 275. A reasonable and responsible drug distributor would have anticipated that excessive diversion of opioids, over a period of years, would lead to devastation across Florida communities.
- 276. Further, the Distributor Defendants were warned repeatedly by governmental agencies that their conduct fell beneath the applicable duty of reasonable care.
- 277. The skyrocketing prescriptions and opioid volume, by itself, was sufficient to alert the Distributor Defendants that opioids were necessarily being diverted from the Distributor Defendants into unlawful channels.
- 278. The Distributor Defendants breached their duties of reasonable care with respect to their distribution of opioids. The Distributor Defendants filled numerous suspicious orders from their Florida customers for at least the past ten years. Consequently, opioids were diverted into unlawful channels—precisely the outcome that the Distributor Defendants' duties were designed to prevent—which in large part created the opioid epidemic.
- 279. The Distributor Defendants breached their duties to maintain effective controls against diversion of opioids.
- 280. The Distributor Defendants' breach of duty is the proximate cause and/or a substantial factor contributing to the damages suffered by the State of Florida and its citizens alleged in this Complaint.
 - 281. The harms to the State of Florida and its citizens were foreseeable in light of the

Distributor Defendants' breach of their duties.

- 282. As alleged throughout this Complaint, the Distributor Defendants' breach of their duties is the proximate cause of the harms described herein.
- 283. The State of Florida seeks damages resulting from the Distributor Defendants' negligence.

Count V <u>Negligence Per Se</u> (Distributor Defendants)

- 284. This is an action against the Distributor Defendants under Florida common law for negligence *per se*.
- 285. Plaintiff State of Florida adopts, realleges, and incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.
- 286. The Office of the Attorney General is entitled to bring claims at common law as the public interest requires and retains wide discretion in making the determination as to the public interest.
- 287. The Florida legislature has stated that careful distribution of controlled substances is "necessary to protect the public health, safety and welfare."
- 288. The Florida Drug and Cosmetic Act ("FDCA") was passed with the intention to "safeguard the public health and promote the public welfare by protecting the public from injury." Fla. Stat. § 499.002(1)(a).
- 289. As a public safety statute, the class of people the FDCA seeks to protect includes the public at large as well as those entities which serve the public, including the State of Florida, its agencies, entities, and municipalities.
 - 290. Consequently, the State of Florida is within the class of people intended to be

protected by the FDCA.

- 291. The FDCA governing the Distributor Defendants' conduct is designed to prevent the diversion of drugs and controlled substances for unlawful purposes and any harm resulting diversion.
- 292. The injuries suffered by the State of Florida and its citizens described above are the type of injuries the FDCA was designed to prevent.
- 293. The Distributor Defendants' repeated violations of the FDCA described above constitute negligence *per se*.
- 294. The Distributor Defendants' repeated violations of the FDCA were the proximate cause of the injuries suffered by the State of Florida and its citizens.
- 295. The State of Florida seeks damages resulting from the Distributor Defendants' negligence *per se*.

Prayer for Relief

WHEREFORE, Plaintiff State of Florida prays for the following relief:

- a. The acts described herein be adjudged unlawful under statutory and common law;
- b. Defendants be enjoined from, either directly or indirectly through third parties, continuing to misrepresent or omit the relative risks and benefits of opioids;
- c. Distributor Defendants be enjoined from failing to report suspicious orders;
- d. Plaintiff recover all measure of damages allowable under statutory and common law, including treble damages;
- e. Plaintiff recover restitution on behalf of Florida agencies and consumers;
- f. Defendants disgorge their ill-gotten proceeds;
- g. Defendants divest themselves of any interest in any enterprise, including real

- property under Florida RICO;
- h. Defendants forfeit any property used in the course of, intended for use in the course of, derived from, or realized through conduct in violation of Florida RICO;
- Reasonable restrictions be imposed upon the future activities or investments of any Defendant under Florida RICO;
- j. The enterprise be dissolved under Florida RICO;
- k. An order be issued suspending or revoking any license, permit, or prior approval granted to the enterprise by any agency of the State under Florida RICO;
- Plaintiff be awarded civil penalties against the Defendants under the Florida
 Deceptive and Unfair Trade Practices Act and Florida RICO;
- m. Plaintiff recover its attorneys' fees, costs of investigation, and other costs as provided by law;
- n. An order abating the public nuisance and ordering any injunctive relief that the Court finds appropriate under law; and
- o. An order awarding such other and further relief as the Court deems appropriate.

Jury Trial Demand

Plaintiff hereby demands a trial by jury on all issues so triable.

Respectfully submitted, this 15th day of May 2018.

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